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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/635,319	08/06/2003	Benjamin Garden	MSDI-67/PC933.00	8113
52196	7590	07/25/2008		
KRIEG DEVAULT LLP ONE INDIANA SQUARE, SUITE 2800 INDIANAPOLIS, IN 46204-2709			EXAMINER SWIGER III, JAMES L	
			ART UNIT	PAPER NUMBER
			3733	
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			07/25/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/635,319	Applicant(s) GARDEN ET AL.	
	Examiner JAMES L. SWIGER III	Art Unit 3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 March 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 8/6/2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-16, and 18-31 are rejected under 35 U.S.C. 102(b) as being unpatentable over Michelson (US Patent 6,193,721) in view of Michelson (US Patent 7,063,702). Michelson discloses a spinal stabilization system positionable along the spinal column, a holding element (60) that includes a distal portion (towards the plate) and proximal portion (92) (56) and an intermediate portions (90/62) therebetween that also has an instrument first engaging portion (considered as 64/65) that is adapted to receive a rotational force from a second portion (68) that is spaced from a first portion adapted to receive a force. It is noted that the top surface of 68 is considered also a second surface of receiving an axial force. The device may also be considered to have a 'distally oriented' engagement surface. The proximal and distal elements are also in cooperation with the auxiliary portion maintain a position along the spine. The retaining device also has a penetrating element (66) that fits into a cannulation with a central aperture (Fig. 32) that also aligns with the aperture of a stabilization system. The retaining device further has a location offset from a number of bone anchor openings that at least

partially overlap at least one of said bone anchor openings. The notches in the retaining member are capable of overlapping the bone anchor openings.

Michelson discloses a spinal stabilization system positionable along the spinal column having at least an auxiliary element mounted thereto (see Figs. 21, 29, 18, or item 20) and wherein the auxiliary element has a hole or cannulation (208/24), a holding element (60) that includes a distal portion (towards the plate) and proximal portion (92) (56) and an intermediate portions (90/62).

The instrument body also has an instrument first engaging portion (considered as 64/65) that is adapted to receive a rotational force from a second portion (68) that is spaced from a first portion adapted to receive a force. It may also be considered to have a 'distally oriented' engagement surface. The proximal and distal elements are also in cooperation with the auxiliary portion maintain a position along the spine. The retaining device also has a penetrating element (66) that fits into a cannulation with a central aperture (Fig. 32) that also aligns with the aperture of a stabilization system.

As a general note, Michelson discloses each and every element as required by applicant's claims. However, Michelson does not disclose, specifically the use of some kind of device that has a distal portion that goes through the claimed auxiliary element, particularly the distal portion of the a holding device going through the cannulation of the auxiliary element. Michelson does, however, teach the use of a distal element coming into contact with the spine to help secure the stabilization system (see Figs. 31 and 33 and Col. 23 lines 18-40). Michelson teaches a similar use, except the distal point goes through the hole in the plate itself, and not through the aux element. Further Michelson

teaches that the distal portion of the holding element is configured (Fig. 32, 71) so that it can grab the plate or screw and provide rotation. In view of this, the above claims are rejected as obvious over re-arrangement of parts. It would have been obvious to one having ordinary skill in the art at the time the invention was made to put the distal end through a different location (one hole versus another), since it has been held that rearranging parts of an invention involves only routine skill in the art. In re Japikse, 86 USPQ 70.

Michelson '721 discloses the claimed invention except for the wherein the entire holding element passes through a stabilization device to the spinal area and wherein further the distal end of the holding element has the ability to interact with an auxiliary element to facilitate rotate or prevent rotation in that regard in assisting with the insertion of the spinal stabilization system.

Michelson '702 has a holding element (see Fig. 1A and 14/15) wherein the distal portion has engaging portions that assist in rotating an auxiliary instrument and inserting a probe-like spike (end of screw) into the spinal area. In terms of Michelson '702, this portion 130 (a lock) can be fixed relative (see 1B) to the spinal anchor and is like the auxiliary element. It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of Michelson '721 having at least the distal engaging portions on the holding element in view of Michelson '702 to have better remote control of the insertion of the spinal apparatus and to more precisely insert a screw or screw-like implement with minimal movement

Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over

Michelson '721 in view of Michelson '702 and further in view of Kuslich et al. (US Publication 2003/0083749). Michelson discloses the claimed invention except for the teaching of the use of the device as a corpectomy implant. Kuslich et al. teaches the use of a stabilization system that is, more specifically, a corpectomy device (pars. 0030 through 0035). It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of Michelson '721 and Michelson '702 that may also be used as a corpectomy device in view of Kuslich et al. to better use the device to stabilize the spine.

Response to Arguments

Applicant's arguments submitted on 3/11/2008 are generally considered moot in light of the new rejections above. It is noted that the auxiliary element still reads on the claimed invention, having a proximal opening facing away from the spine and a distal opening towards the spine. Also with regard to rotational and anti-rotational movement, this can be a relative functional limitation, depending on the situation. The device can be rotated, but the structure of the device could also prevent rotation relative to the device, as the auxiliary instrument is interfaced with the distal portion of the holding element in a relationship.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAMES L. SWIGER III whose telephone number is (571)272-5557. The examiner can normally be reached on Monday through Friday, 9:00am to 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3733

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/JAMES L SWIGER/
Examiner, Art Unit 3733
/Eduardo C. Robert/
Supervisory Patent Examiner, Art Unit 3733